

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
DESIGNATED/ELECTED OFFICE (DO/EO/US)**

First Named
Inventor: J. Mark Sutton

Serial No.: 10/599,098

International
Application No. PCT/GB05/01056 Examiner: Not yet assigned

International Filing
Date: March 22, 2005 Group Art Unit No.: 1657

Title: BIOLOGICAL INDICATOR Confirmation No.: 4054

**Response to Notification of Missing Requirements Under 35 U.S.C. 371 In
the United States Designated/Elected Office (DO/EO/US)**

M.S. – PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450


Dear Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 In the United States
Designated/Elected Office (DO/EO/US) dated June 29, 2009, enclosed herewith for filing are the following
documents:

1. Electronic Credit Card Payment (form not included)
2. Response to Notification of Missing Requirements Under 35 U.S.C. 371 In the United States
Designated/Elected Office (DO/EO/US)
3. Copy of Original Notification of Missing Requirements Under 35 U.S.C. 371 In the United States
Designated/Elected Office (DO/EO/US)
4. Declaration (2 pages)
5. Power of Attorney and Statement under 37 CFR 3.73 (b) (with copy of assignment)
6. Statement to Support Filing and Submission in Accordance with 37 C.F.R. §§ 1.821-1.825
7. Sequence Listing txt file

Large entity - Payment by credit card.

Respectfully submitted,



Paul E. Rauch, Ph.D.
Registration No. 38,591

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UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
10/599,098	Mark J. Sutton	MSQ01-007-US

43320
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INTERNATIONAL APPLICATION NO.	
PCT/GB05/01056	
I.A. FILING DATE	PRIORITY DATE
03/22/2005	03/22/2004

CONFIRMATION NO. 4054
371 FORMALITIES LETTER

Evan Law Group LLC



Date Mailed: 06/29/2009

**NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371
IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)**

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as an Elected Office (37 CFR 1.495):

- Priority Document
- Copy of the International Application filed on 09/19/2006
- Copy of the International Search Report filed on 09/19/2006
- Copy of IPE Report filed on 09/19/2006
- Preliminary Amendments filed on 09/19/2006
- Information Disclosure Statements filed on 02/22/2007
- Biochemical Sequence Listing filed on 09/19/2006
- U.S. Basic National Fees filed on 09/19/2006
- Priority Documents filed on 09/19/2006
- Specification filed on 09/19/2006
- Claims filed on 09/19/2006
- Abstracts filed on 09/19/2006
- Drawings filed on 09/19/2006
- Paper Computer Listings filed on 09/19/2006

The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is **\$780** for a Large Entity:

- **\$130** Surcharge
- This application does not contain a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

Applicant must provide such statement. If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000).

- A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 CFR 1.821(e). If the effective filing date is on or after September 8, 2000, see the final rulemaking notice published in the Federal Register at 65 FR 54604 (September 8, 2000) and 1238 OG 145 (September 19, 2000). Applicant must provide an initial computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the U.S. Patent and Trademark Office, such request in accordance with 37 CFR 1.821(e) may be submitted in lieu of a new CRF.
- The application search fee has not been paid. Applicant must submit **\$430** to complete the search fee. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.
- The application examination fee has not been paid. Applicant must submit **\$220** to complete the examination fee for a non-small entity. Note a surcharge will be required if submitted later than commencement of the national stage (37 CFR 1.492(h)) and the basic national fee was not paid before July 1, 2005.

Applicant is cautioned that correction of the above items may cause the specification and drawings page count to exceed 100 pages. If the specification and drawings exceed 100 pages, applicant will need to submit the required application size fee.

For questions regarding compliance to 37 CFR 1.821-1.825 requirements, please contact:

- **For Rules Interpretation, call (571) 272-0951**
- **For Patentin Software Program Help, call Patent EBC at 1-866-217-9197 or directly at 703-305-3028 / 703-308-6845 between the hours of 6 a.m. and 12 midnight, Monday through Friday, EST.**
- **Send e-mail correspondence for Patentin Software Program Help @ ebc@uspto.gov**

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.

<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at **1-866-217-9197** or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

FREDERICK SMITH

Telephone: (703) 756-1455

SEQUENCE LISTINGS AND TABLES RELATED THERETO IN INTERNATIONAL APPLICATIONS FILED IN THE U.S. RECEIVING OFFICE

The Administrative Instructions (AIs) under the Patent Cooperation Treaty (PCT), in force as of **July 1, 2009**, contain important changes relating to the manner of filing, and applicable fees for, sequence listings and/or tables related thereto (sequence-related tables) in international applications. The complete text may be accessed at <http://www.wipo.int/pct/en/texts/index.htm>.

Effective July 1, 2009, Part 8 and Annex C-*bis* will no longer form part of the AIs. Part 8 was introduced in 2001 as a temporary solution to problems arising from the filing of very large sequence listings on paper and provided for a *sequence listing forming part of the international application* to be filed in electronic form on physical medium (e.g., CD), together with the remainder of the application on paper. In 2002, Part 8 was expanded to include sequence-related tables and Annex C-*bis* was added to provide technical requirements. All applicants may now file complete international applications in electronic form, eliminating the need for these temporary provisions.

I. AIS PART 8 AND ANNEX C-BIS DELETED AS OF JULY 1, 2009

- A) **Sequence-related tables cannot be filed as a separate part of the description or in text format.** They must be provided as an integral part of the international application either:
- in PDF format as part of an international application filed in electronic form via EFS-Web; or
 - on paper as part of an international application filed on paper.
- B) A *sequence listing forming part of an international application* may be provided either:
- in electronic form, as part of an international application filed in electronic form via EFS-Web, in
 - Annex C/ST.25 text format (preferred), or
 - PDF format; or
 - on paper as part of an international application filed on paper.
- C) A *sequence listing not forming part of the international application* (for search under PCT Rule 13ter) in Annex C/ST.25 text format
- is not required where the *sequence listing forming part of the international application* was filed in Annex C/ST.25 text format as part of an international application filed in electronic form via EFS-Web
 - is required for search where the *sequence listing forming part of the international application* was filed in PDF
 - is required for search on physical medium (e.g., CD) where the *sequence listing forming part of the international application* was filed on paper as part of an international application filed on paper.

II. CALCULATION OF THE INTERNATIONAL FILING FEE AND FEE REDUCTION UNDER AI § 707

- A) A **sequence-related table** must form an integral part of the international application and will incur FULL page fees with no upper limit.
- B) A *sequence listing forming part of an international application* filed:
- via EFS-Web in Annex C/ST.25 text format will incur NO page fees;
 - on paper or in PDF format will incur FULL page fees with no upper limit.

III. AVAILABILITY OF SEQUENCE LISTINGS SUBMITTED FOR SEARCH UNDER PCT RULE 13TER

International Searching Authorities will be required to transmit to the International Bureau a copy of an Annex C/ST.25 text format sequence listing provided for search under PCT Rule 13ter. Any such sequence listing will be made available on PATENTSCOPE® (*sequence listings forming part of the international application* are already available).

IV. JULY 2009 REQUEST (PCT/RO/101)

The Request now has two options for the last sheet: one for paper filings; and one for EFS-Web filings. The July 2009 Request may be accessed at <http://www.wipo.int/pct/en/forms/index.htm>.